2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk

Endorsed by the American Association of Cardiovascular and Pulmonary Rehabilitation, American Society for Preventive Cardiology, American Society of Hypertension, Association of Black Cardiologists, National Lipid Association, Preventive Cardiovascular Nurses Association, and WomenHeart: The National Coalition for Women with Heart Disease

Citation

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ACC/AHA Risk Assessment Guideline Work Group

David C. Goff, Jr, MD, PhD, FACP, FAHA, *Co-Chair*
Donald M. Lloyd-Jones, MD, ScM, FACC, FAHA, *Co-Chair*

Glen Bennett, MPH*
Sean Coady, MS*
Ralph B. D'Agostino, Sr, PhD, FAHA
Raymond Gibbons, MD, FACC, FAHA
Philip Greenland, MD, FACC, FAHA
Daniel T. Lackland, DrPH, FAHA
Daniel Levy, MD*
Christopher J. O'Donnell, MD, MPH*
Jennifer Robinson, MD, MPH, FAHA
J. Sanford Schwartz, MD
Susan T. Shero, MS, RN*
Sidney C. Smith, Jr, MD, FACC, FAHA
Paul Sorlie, PhD*
Neil J. Stone, MD, FACC, FAHA
Peter W.F. Wilson, MD, FAHA

*Ex-Officio Members.

Acknowledgements

Methodology Members
Harmon S. Jordan, ScD
Lev Nevo, MD
Janusz Wnek, PhD

National Heart, Lung, and Blood Institute
Denise Simons-Morton, MD, PhD

Conflict of Interest/ Relationships with Industry

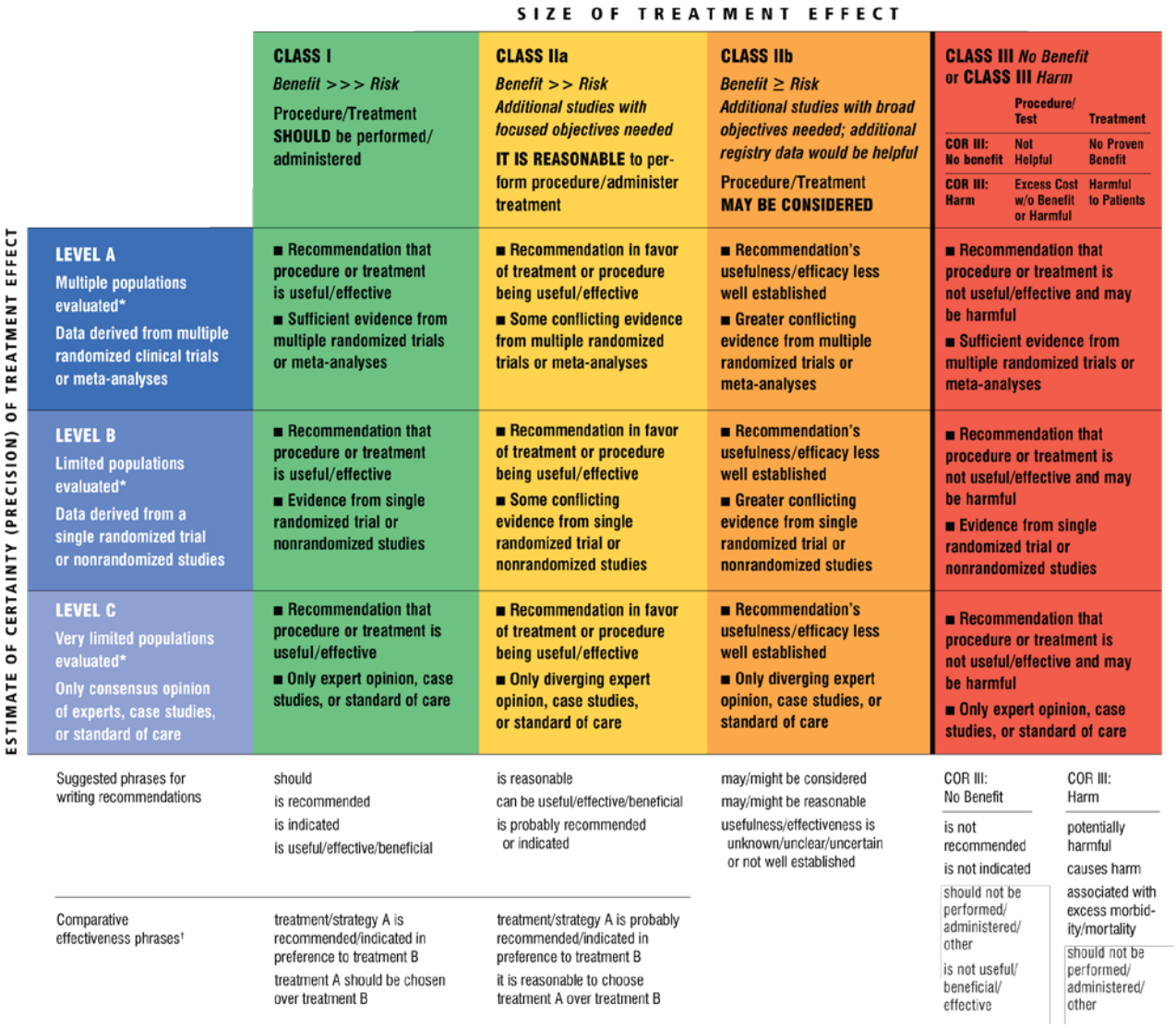
1) Majority of Work Group members had none; all panel members disclosed COI/RWI information to the full panel in advance of any deliberations

2) Members with COI/RWI (N=5/17) prohibited from voting on any aspect of the guideline where a conflict might exist

3) All 17 members of the NHLBI Risk Assessment Work Group transitioned to the ACC/AHA Expert Work Group

4) Independent contractors performed the systematic review with the assistance of the Expert Panel and provided methodological guidance to the Expert Panel

Classification of Recommendations and Levels of Evidence



SIZE OF TREATMENT EFFECT

ESTIMATE OF CERTAINTY (PRECISION) OF TREATMENT EFFECT

	CLASS I *Benefit >>> Risk* Procedure/Treatment **SHOULD** be performed/ administered	CLASS IIa *Benefit >> Risk* *Additional studies with focused objectives needed* **IT IS REASONABLE** to perform procedure/administer treatment	CLASS IIb *Benefit ≥ Risk* *Additional studies with broad objectives needed; additional registry data would be helpful* Procedure/Treatment **MAY BE CONSIDERED**	CLASS III *No Benefit* or CLASS III *Harm* Procedure/ Test / Treatment COR III: No benefit — Not Helpful — No Proven Benefit COR III: Harm — Excess Cost w/o Benefit or Harmful — Harmful to Patients
LEVEL A Multiple populations evaluated* Data derived from multiple randomized clinical trials or meta-analyses	■ Recommendation that procedure or treatment is useful/effective ■ Sufficient evidence from multiple randomized trials or meta-analyses	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from multiple randomized trials or meta-analyses	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Sufficient evidence from multiple randomized trials or meta-analyses
LEVEL B Limited populations evaluated* Data derived from a single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is useful/effective ■ Evidence from single randomized trial or nonrandomized studies	■ Recommendation in favor of treatment or procedure being useful/effective ■ Some conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation's usefulness/efficacy less well established ■ Greater conflicting evidence from single randomized trial or nonrandomized studies	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Evidence from single randomized trial or nonrandomized studies
LEVEL C Very limited populations evaluated* Only consensus opinion of experts, case studies, or standard of care	■ Recommendation that procedure or treatment is useful/effective ■ Only expert opinion, case studies, or standard of care	■ Recommendation in favor of treatment or procedure being useful/effective ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation's usefulness/efficacy less well established ■ Only diverging expert opinion, case studies, or standard of care	■ Recommendation that procedure or treatment is not useful/effective and may be harmful ■ Only expert opinion, case studies, or standard of care
Suggested phrases for writing recommendations	should is recommended is indicated is useful/effective/beneficial	is reasonable can be useful/effective/beneficial is probably recommended or indicated	may/might be considered may/might be reasonable usefulness/effectiveness is unknown/unclear/uncertain or not well established	COR III: No Benefit: is not recommended; is not indicated COR III: Harm: potentially harmful; causes harm; associated with excess morbidity/mortality
Comparative effectiveness phrases†	treatment/strategy A is recommended/indicated in preference to treatment B treatment A should be chosen over treatment B	treatment/strategy A is probably recommended/indicated in preference to treatment B it is reasonable to choose treatment A over treatment B		COR III: No Benefit: should not be performed/ administered/ other; is not useful/ beneficial/ effective COR III: Harm: should not be performed/ administered/ other

A recommendation with Level of Evidence B or C does not imply that the recommendation is weak. Many important clinical questions addressed in the guidelines do not lend themselves to clinical trials. Although randomized trials are unavailable, there may be a very clear clinical consensus that a particular test or therapy is useful or effective.

*Data available from clinical trials or registries about the usefulness/ efficacy in different subpopulations, such as sex, age, history of diabetes, history of prior myocardial infarction, history of heart failure, and prior aspirin use.

†For comparative effectiveness recommendations (Class I and IIa; Level of Evidence A and B only), studies that support the use of comparator verbs should involve direct comparisons of the treatments or strategies being evaluated.

NHLBI Charge to the Work Group

- Examine the scientific evidence on risk assessment for initial ASCVD events, and develop an approach for risk assessment that could be used in practice and used or adapted by the risk factor panels in their guidelines.

- Specifically, the Work Group was charged with 2 tasks:
  1. To develop or recommend an approach to quantitative risk assessment that could be used to guide care; and
  2. To pose and address a small number of questions judged to be critical to refining and adopting risk assessment in clinical practice, using systematic review methodology.

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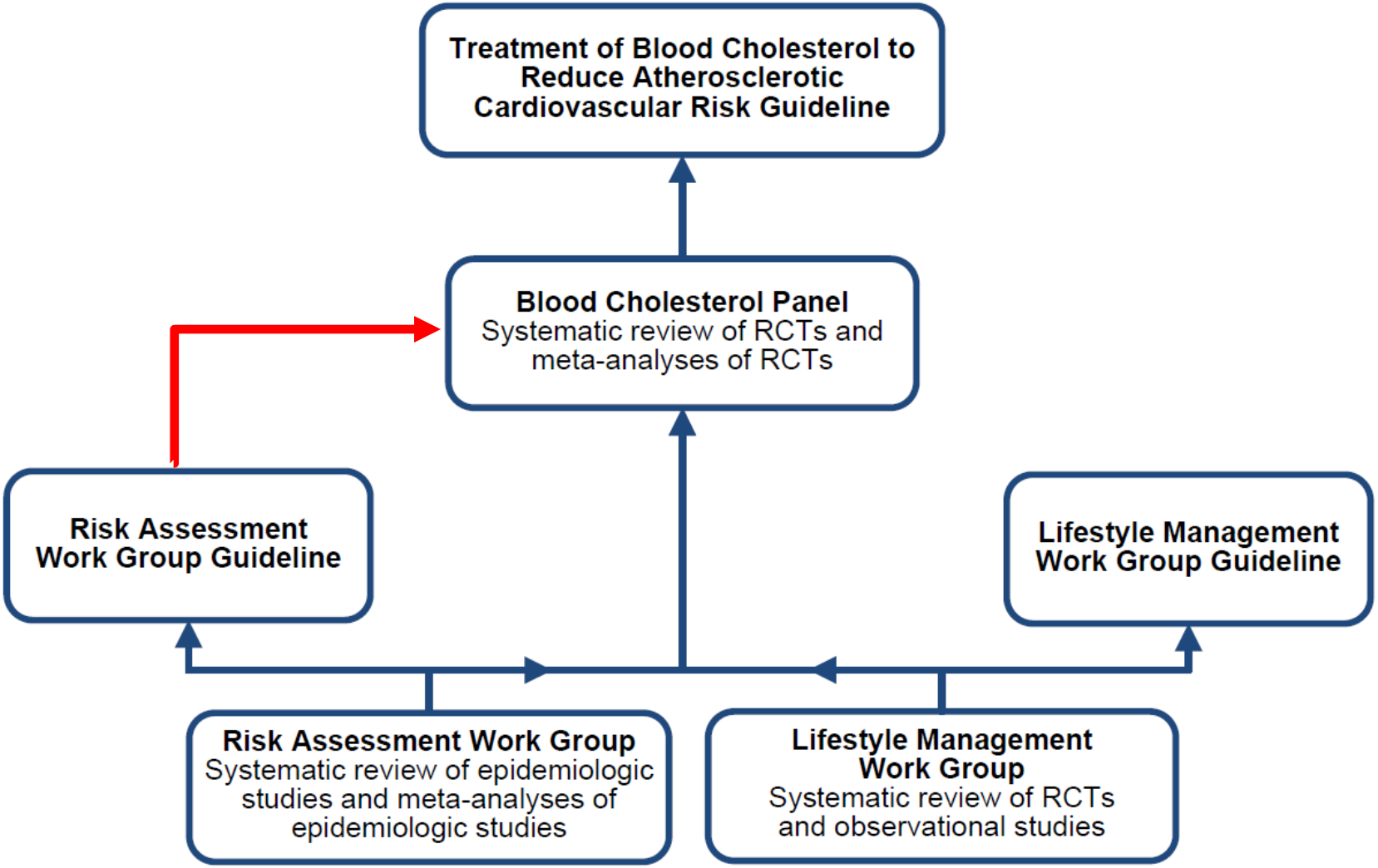

Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk Guideline
Blood Cholesterol Panel
Systematic review of RCTs and meta-analyses of RCTs
Risk Assessment Work Group Guideline
Lifestyle Management Work Group Guideline
Risk Assessment Work Group
Systematic review of epidemiologic studies and meta-analyses of epidemiologic studies
Lifestyle Management Work Group
Systematic review of RCTs and observational studies

ASCVD Risk Calculator
Considerations

- RAWG endorsed the paradigm of 10-year risk estimation
- Existing risk scores vary with regard to:
  - Derivation populations
    - Age, sex, race, birth cohort, country/region of origin
  - Inputs
    - Traditional RFs ± family hx, BMI, SES, region, CRP
  - Outcomes
    - CVD death, Total CHD (incl revasc), Total CHD, Hard CHD, Total CVD (revasc), Hard CVD (incl HF)

ASCVD Risk Calculator
Development

- RAWG judged new risk tool was needed
  - Inclusive of African Americans and with expanded endpoint including stroke
- Sought cohorts representative of the US population as a whole
  - Community- or population-based
  - Whites and African Americans (at a minimum)
  - Recent follow up data of at least 10 years
    - Reflect more contemporary risk factor trends and event rates, ideally without significant downstream uptake of statins/revascularization

ASCVD Risk Calculator
Development

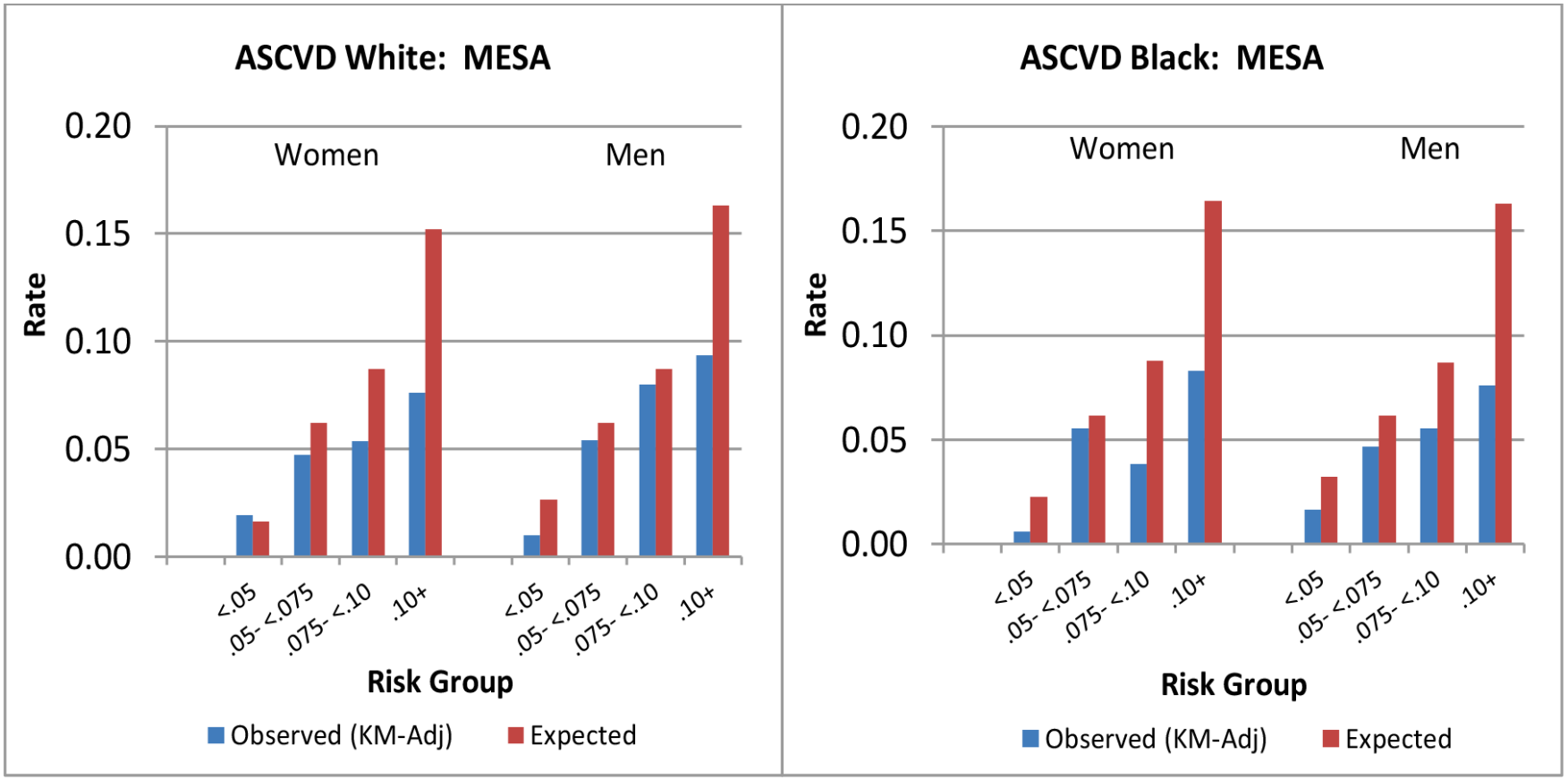
- Pooled Cohort Equations
  - Atherosclerosis Risk in Communities (ARIC)
  - Cardiovascular Heath Study (CHS)
  - Coronary Artery Risk Development in Young Adults (CARDIA)
  - Framingham Original and Offspring
- Hard ASCVD
  - CHD death, non-fatal MI, fatal/non-fatal stroke
- Models tested using traditional RFs + newer markers when possible
- Internal and external validation

ASCVD Risk Calculator

Model Characteristics

	White Women	AA Women	White Men	AA Men
N	11,240	2641	9098	1647
Age Range	40-79	40-79	40-79	40-79
C statistic	0.81	0.82	0.75	0.71
Calibration X^2	6.43	7.25	4.86	6.71

External Validation: MESA



ASCVD Risk Calculator

Search “ACC/AHA Prevention Guidelines risk calculator”

American Heart Association.

AMERICAN COLLEGE of CARDIOLOGY

2013 Prevention Guidelines Tools

CV RISK CALCULATOR

The American Heart Association and the American College of Cardiology are excited to provide a series of new cardiovascular prevention guidelines for the assessment of cardiovascular risk, lifestyle modifications that reduce risk, management of elevated blood cholesterol, and management of increased body weight in adults. To support the implementation of these guidelines, the new Pooled Cohort Equations CV Risk Calculator and additional Prevention Guideline Tools are available below. Others may be developed and available in the near future.

DOWNLOAD CV RISK CALCULATOR

This downloadable spreadsheet is a companion tool to the **2013 ACC/AHA Guideline on the Assessment of Cardiovascular Risk**. The spreadsheet enables health care providers and patients to estimate 10-year and lifetime risks for atherosclerotic cardiovascular disease (ASCVD), defined as coronary death or nonfatal myocardial infarction, or fatal or nonfatal stroke, based on the Pooled Cohort Equations and the work of Lloyd-Jones, et al., respectively. The information required to estimate ASCVD risk includes age, sex, race, total cholesterol, HDL cholesterol, systolic blood pressure, blood pressure lowering medication use, diabetes status, and smoking status.

Estimates of 10-year risk for ASCVD are based on data from multiple community-based populations and are applicable to African-American and non-Hispanic white men and women 40 through 79 years of age. For other ethnic groups, we recommend use of the equations for non-Hispanic whites, though these estimates may underestimate the risk for persons from some race/ethnic groups, especially American Indians, some Asian Americans (e.g., of south Asian ancestry), and some Hispanics (e.g., Puerto Ricans), and may overestimate the risk for others, including some Asian Americans (e.g., of east Asian ancestry) and some Hispanics (e.g., Mexican Americans).

Estimates of lifetime risk for ASCVD are provided for adults 20 through 59 years of age and are shown as the lifetime risk for ASCVD for a 50-year old without ASCVD who has the risk factor values entered into the spreadsheet. The estimates of lifetime risk are most directly applicable to non-Hispanic whites. We recommend the use of these values for other race/ethnic groups, though as mentioned above, these estimates may represent under- and overestimates for persons of various ethnic groups. Because the primary use of these lifetime risk estimates is to facilitate the very important discussion regarding risk reduction through lifestyle change, the imprecision introduced is small enough to justify proceeding with lifestyle change counseling informed by these results.

Figure 1. Implementation of Risk Assessment Work Group Recommendations

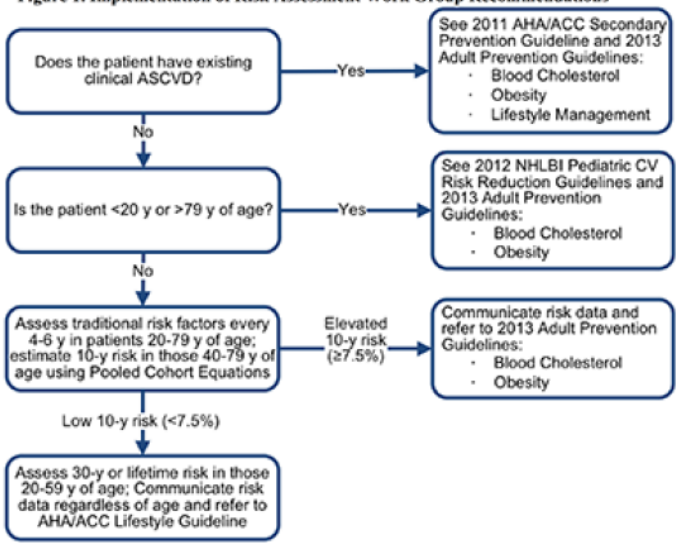


Figure 1. Implementation of Risk Assessment Work Group Recommendations

Clinical Vignettes

ASCVD Risk Calculator

Pooled Cohort Equations

Risk Factor	Units	Value	Acceptable range of values	Optimal values
Sex	M or F		M or F	
Age	years		20-79	
Race	AA or WH		AA or WH	
Total Cholesterol	mg/dL		130-320	170
HDL-Cholesterol	mg/dL		20-100	50
Systolic Blood Pressure	mm Hg		90-200	110
Treatment for High Blood Pressure	Y or N		Y or N	N
Diabetes	Y or N		Y or N	N
Smoker	Y or N		Y or N	N

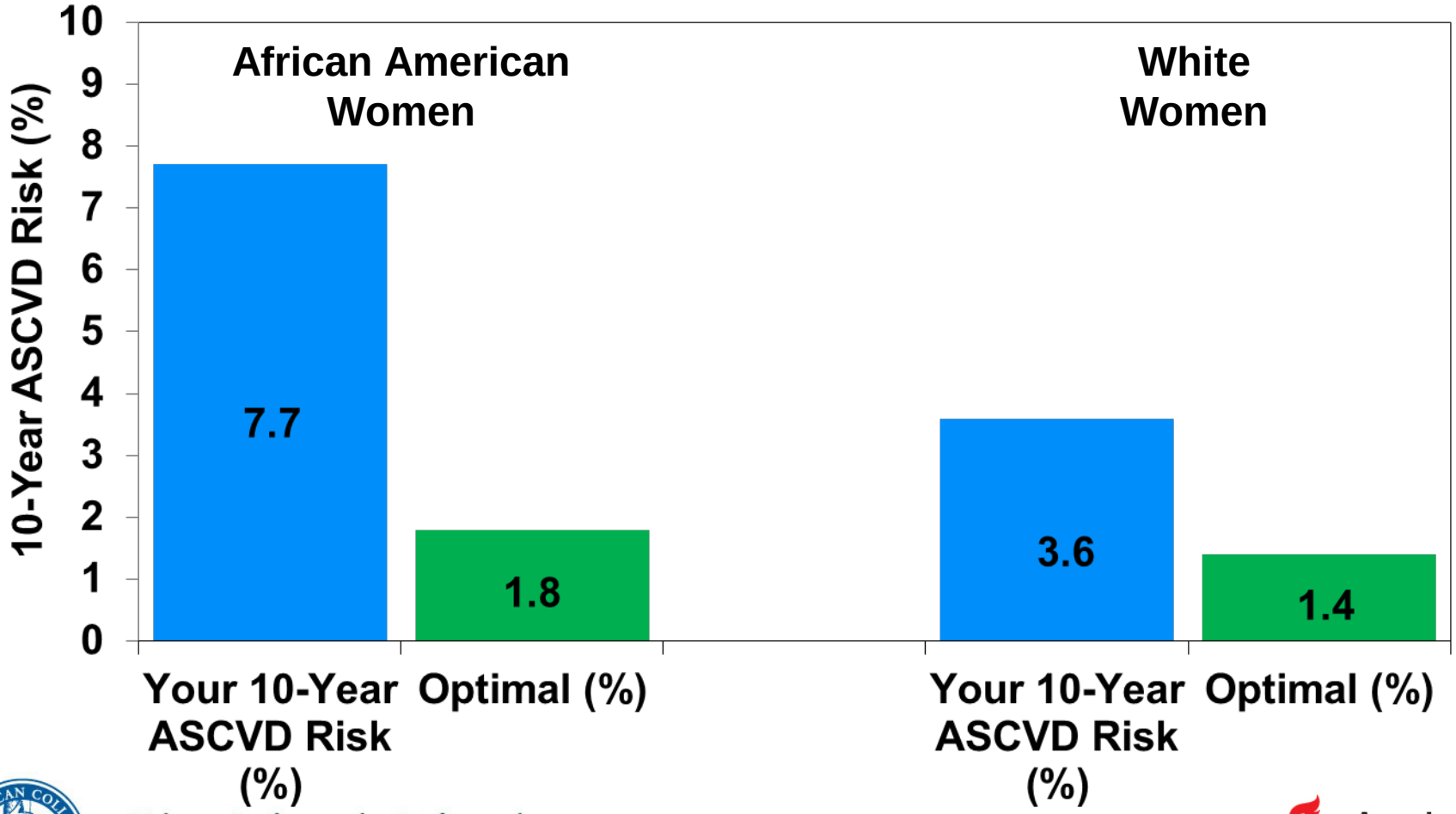
ASCVD Risk Calculator

Pooled Cohort Equations

Risk Factor	Units	Value	Acceptable range of values	Optimal values
Sex	M or F	**F**	M or F	
Age	years	**55**	20-79	
Race	AA or WH	**AA**	AA or WH	
Total Cholesterol	mg/dL	**210**	130-320	170
HDL-Cholesterol	mg/dL	**56**	20-100	50
Systolic Blood Pressure	mm Hg	**145**	90-200	110
Treatment for High Blood Pressure	Y or N	**Y**	Y or N	N
Diabetes	Y or N	**N**	Y or N	N
Smoker	Y or N	**N**	Y or N	N

ASCVD Risk Calculator

55 yo AA and White Women



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Recommendations for 10-Year ASCVD Risk Estimation

The race- and sex-specific Pooled Cohort Equations to predict 10-year risk for a first hard ASCVD event should be used in non-Hispanic African Americans and non-Hispanic Whites, 40 to 79 years of age.

Use of the sex-specific Pooled Cohort Equations for non-Hispanic Whites may be considered when estimating risk in patients from populations other than African Americans and non-Hispanic Whites.

NHLBI Charge to the Work Group

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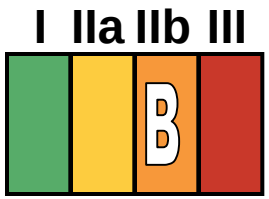
Systematic Review Process

- CQs relevant to clinical practice
- A priori inclusion/exclusion (I/E) criteria
- Independent contractor conducted literature search
- Literature search through April, 2011
- Updated search for CQ#1 through September, 2013

Critical Question #1

- CQ1: “What is the evidence regarding reclassification or contribution to risk assessment when the following are considered in addition to the variables that are in the traditional risk scores?”
  - High-sensitivity C-reactive protein (hs-CRP)
  - Apolipoprotein B (ApoB)
  - Glomerular filtration rate (eGFR)
  - Microalbuminuria
  - Family history
  - Cardiorespiratory fitness
  - Ankle-brachial index (ABI)
  - Carotid intima-media thickness (CIMT)
  - Coronary artery calcium (CAC) score

Recommendations for Additional Testing if Uncertainty Remains After 10-Year Risk Assessment



If, after quantitative risk assessment, a risk-based treatment decision is uncertain, assessment of 1 or more of the following — family history, hs-CRP, CAC score, or ABI — may be considered to inform treatment decision making.

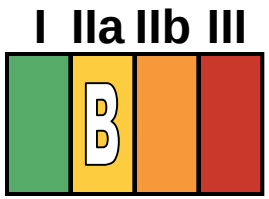
CIMT is not recommended for routine measurement in clinical practice for risk assessment for a first ASCVD event. (Class III – No Benefit)

Critical Question #2

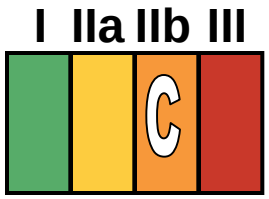
- CQ2: “Are models constructed to assess the long-term (15 years or lifetime) risk for a first CVD event in adults effective in assessing variation in long-term risk among adults at low and/or intermediate short-term risk, whether analyzed separately or combined?”

- Developed to assess the utility of long-term and lifetime risk assessment as an adjunct to short-term (10-year) risk assessment
  - Especially among those at low 10-year risk

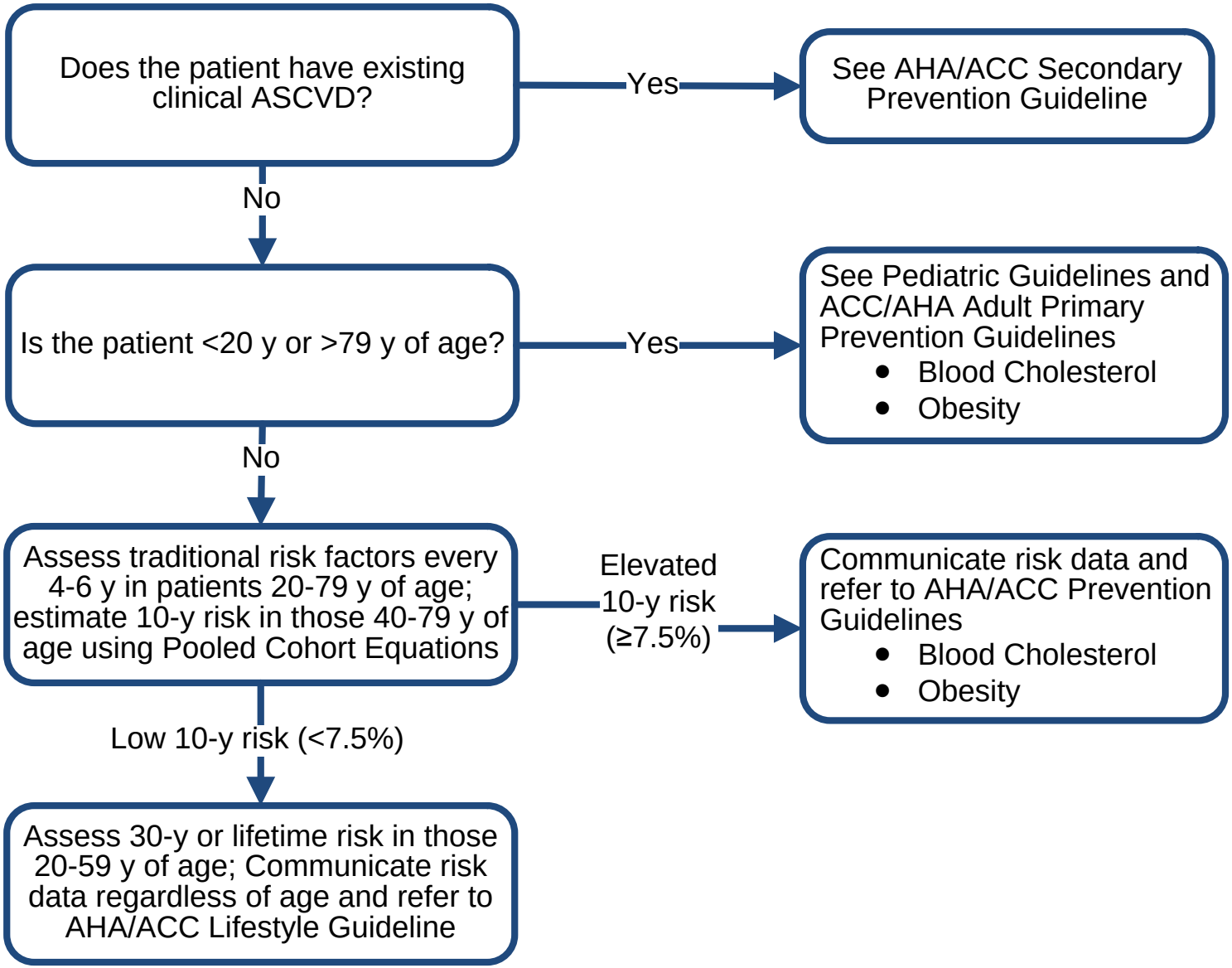
Recommendations for Long-Term ASCVD Risk Estimation



It is reasonable to assess traditional ASCVD risk factors every 4 to 6 years in adults 20 to 79 years of age who are free from ASCVD and to estimate 10-year ASCVD risk every 4 to 6 years in adults 40 to 79 years of age without ASCVD.



Assessing 30-year or lifetime ASCVD risk based on traditional risk factors may be considered in adults 20 to 59 years of age without ASCVD and who are not at high short-term risk.



Evidence Gaps and Future Research Needs

- The Work Group strongly recommends continued research to fill gaps in knowledge
  - Short- and long-term ASCVD risk assessment and outcomes in all age/sex/race groups
  - Optimal communication of ASCVD risk
  - Utility of risk assessment for motivating behavioral change and adherence to therapy
  - Utility of differential information conveyed by short- and long-term risk assessment
  - Utility of novel risk markers and disease screening in short- and long-term risk assessment